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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Anxiety disorders are extremely common among individuals with autism spectrum disorder (ASD). The presence of an anxiety disorder negatively affects family functioning, friendship development, and school functioning. Our long term goal is to be able to identify children with ASD who are at risk for anxiety as early as possible so that early intervention can address not only ASD symptoms, but also target specific symptoms that put a child with ASD at risk for developing an anxiety disorder. During the second year of funding we have focused on data collection, data quality control, and preliminary data analyses. Preliminary analyses suggest that, in our convenience sample, 79% of children meet criteria for an impairing anxiety disorder, 21% of children score at least 1 standard deviation above the group mean for sensory over-responsivity (SOR), and 100% of children in the SOR group also meet criteria for an anxiety disorder, however only 30% of children who meet criteria for an anxiety disorder are in the SOR group.

15. SUBJECT TERMS

Autism, anxiety, sensory over-responsivity

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I. Introduction

Anxiety disorders are extremely common among individuals with Autism **(**ASD**)**, yet we still know very little about the early risk factors for anxiety in ASD. Research is beginning to provide some clues regarding early risk factors for anxiety in individuals with ASD, suggesting that sensory over-responsivity (SOR) may be an early emerging risk factor for anxiety in individuals with ASD. Our goal is to identify early risk factors for anxiety disorders in individuals with ASD by conducting an in-depth study of the relationship between SOR, attention, and anxiety symptoms in preschool age children with ASD, using parent report, observational, and EEG measures. This project will help identify the early risk factors for anxiety disorders in ASD, which may ultimately allow interventions to focus on prevention of anxiety. If an association between SOR and anxiety symptoms is confirmed, this study will set the stage for a program of research by our group focused on early detection and prevention of anxiety disorders in young children with ASD.

II. Keywords

Autism, Anxiety, Sensory Over-Responsivity, Attention, EEG

III. Accomplishments

A. Major goals of the project

Specific Aim 1: Evaluate the relationship between Sensory Over-reactivity (SOR) and anxiety symptoms/ disorders in a sample of 3-5 year old children with ASD using parent report, observational, and neurophysiological measures.

	Statement of Work Goal Completion Date	**Actual Completion Date or Progress**		
		Site 1 - Duke Dawson, Initiating PI	**Site 2 - Duke** Carpenter, Partnering PI	**Site 3 - UNC** Baranek, Partnering PI
Major Task 1: Prepare regulatory documents and research protocol for IRB and HRPO Approval				
Milestone # 1: IRB approval received at both Duke University and UNC Chapel Hill	12/29/2014	7/21/2014	7/21/2014	6/18/2014
Milestone # 2: HRPO approval received	3/29/2015	8/8/2014	8/8/2014	8/8/2014
Major Task 2: Hiring and training of study personnel on observational measures				
Milestone # 3: Study personnel achieves reliability on the Sensory Processing Assessment, Tactile Defensiveness and Discrimination Test, PAPA, ADOS, and ADI	3/29/2015	7/1/2015	8/1/2015	6/26/2015
Major Task 3: Set up, test, calibrate and pilot experimental measures of attention and neurophysiology				

Milestone #4: Experimental paradigms set-up, tested, and calibrated	3/29/2015	1/22/2015	5/14/2015	5/14/2015
Milestone #5: Study personnel trained in administration of and data collection for attention and ERP tasks	3/29/2015	1/22/2015	5/14/2015	5/14/2015
Milestone #6: Attention and ERP tasks piloted and finalized	4/30/2015	4/3/2015	5/14/2015	5/14/2015
Milestone #7: Study is ready for implementation	4/30/2015	5/14/2015	5/14/2015	5/14/2015
Major Task 4: Participant recruitment and launch of testing				
Milestone # 8: Target enrollment of 30 participants for year 1 reached	9/29/2015	3/29/2016	3/29/2016	3/29/2016
Major Task 5: On-going enrollment and testing of participants and data collection and processing				
Milestone # 9: Target enrollment of 100 participants by end of Q1 of third year reached and data ready for analysis	12/29/2016	48%	48%	48%
Milestone # 10: EEG, eye-tracking and sensory observation task data prepared for analysis.	12/29/2016	48%	48%	48%
Major Task 6: Data analysis of SOR and anxiety measures and publication				
Milestone #11: Complete analysis of SOR and anxiety measures	6/29/2017	48%	48%	48%
Milestone #12: Publish results of study on risk factors for anxiety in young children with ASD.	9/29/2017	0%	0%	0%

Specific Aim 2 Evaluate whether anxiety symptoms/disorders mediate the relationship between SOR and a wide range of negative outcomes that have been associated with SOR, namely, levels of impaired adaptive behavior, challenging behaviors (e.g. irritability, aggression), GI symptoms and parental stress.

	Statement of Work Goal Completion Date	**Actual Completion Date or Progress**		
		Site 1 - Duke Dawson, Initiating PI	**Site 2 - Duke** Carpenter, Partnering PI	**Site 3 - UNC** Baranek, Partnering PI
Major Task 1: Data analysis of comprehensive set of measures and publication				
Milestone #13: Complete analyses on anxiety as a mediator of the impact of SOR on	6/29/2017	0%	0%	0%

negative outcomes for children with ASD				
Milestone #14: Publish study on the role of anxiety as a mediator of the impact of SOR on negative outcomes for children with ASD.	9/29/2017	0%	0%	0%

Specific Aim 3 Evaluate whether attentional control, as assessed by a visual attention-shifting task and event-related potentials (ERPs), moderate the relationship between SOR and anxiety symptoms/disorders.

	Statement of Work Goal Completion Date	**Actual Completion Date or Progress**		
		Site 1 - Duke Dawson, Initiating PI	**Site 2 - Duke** Carpenter, Partnering PI	**Site 3 - UNC** Baranek, Partnering PI
Major Task 1: Automated coding of visual attention task from videotapes - Work to be conducted by Jordan Hashemi under the supervision of Dr. Sapiro in collaboration with Dr. Carpenter				
Milestone #15: Finalize algorithm for data capture.	3/29/2016	N/A	5/1/2016	N/A
Milestone #16: Apply automated coding to videotapes (N = 100)	12/29/2016	N/A	48%	N/A
Major Task 2: Data analysis of attention measures and publication - Work to be conducted by Jordan Hashemi under the supervision of Drs. Sapiro, Carpenter, and Dawson				
Milestone #17: Complete data analysis of all eye-tracking and automated coding data	6/29/2017	48%	48%	48%
Milestone #18: Results of study on automated coding as a valid measure of attention in young children with ASD are published	9/29/2017	0%	0%	0%
Major Task 3: Data analysis of SOR measures (parent report, observation, ERP) and publication				
Milestone #19: Complete data analyses of SOR measures	6/29/2017	48%	48%	48%
Milestone #20: Publish results of study validating an auditory ERP measure as a biomarker of SOR in young children with ASD	9/29/2017	0%	0%	0%

B. Accomplishments under the goals of the project (9/30/2015 through 9/29/2016)

Specific Aim 1. Evaluate the relationship between sensory over-responsivity (SOR) and anxiety symptoms/disorders in a sample of 3-5 year old children with ASD using parent report, observational, and neurophysiological measures.

a. Major Task 1: Prepare regulatory documents and research protocol for IRB and HRPO Approval.

Objective 1: Obtain IRB approval from Duke University and UNC Chapel Hill. – completed in Year 1.

Objective 2: Submit amendments, adverse events, and protocol deviations as needed.

As the project develops, we will continue to amend our IRB to reflect any changes made. Once approved at both sites, amendments to the IRB will also be submitted to the HRPO.

b. Major Task 2: Hiring and training of study personnel on observational measures – completed in Year 1.

In addition to the original training of study personnel, we hired new research assistants in year 2 who have undergone training in cognitive assessments, sensory assessments, and the Preschool Age Psychiatric Assessment. These assistants have joined the rest of the research team in ongoing reliability training activities.

c. Major Task 3: Set up, test, calibrate and pilot experimental measures of attention and neurophysiology – completed in Year 1.

d. Major Task 4: Participant recruitment and launch of testing.

Objective 1: Provide information and flyers about study to all recruitment sites.

We have been actively recruiting subjects through the Duke Center for Autism Subject Registry and have been distributing study brochures to local agencies and at a number of local events (e.g. Autism Speaks Walks, etc.).

Objective 2: Begin screening and enrolling participants in study – completed in year 1.

Objective 3: Maintain reliability and quality control on all measures.

Training to ensure reliability of the assessments is ongoing. Study staff attend monthly ADOS reliability sessions, as well as monthly reliability sessions for the sensory assessments, which take place at the UNC site for this study.

Objective 4: Target enrollment of 30 participants for year 1 reached – completed year 2, quarter 2.

e. Major Task 5: On-going enrollment and testing of participants and data collection and processing.

Objective 1: Continue active recruitment through on-going communication with recruitment sites

We have continued to receive study referrals from the Duke Center for Autism and Brain Development subject registry and distribute study information at all local autism events (e.g. Walk Now for Autism Speaks, Autism Society of North Carolina Walk, etc.).

Objective 2: Maintain reliability and quality control on all measures.

Training to ensure reliability of the assessments is ongoing. Study staff attend monthly ADOS reliability sessions, as well as monthly reliability sessions for the sensory assessments, which take place at the UNC site for this study

Objective 3: Target enrollment of 100 participants by end of Q1of third year reached and data ready for analysis.

We have enrolled 48 subjects.

Objective 4: Edit and process EEG data for analysis.

Editing and processing of the EEG data occurs as it is collected so that it is ready for analysis at the end of data collection.

Objective 5: Process eye-tracking data for analysis.

Editing and processing of the eye-tracking data occurs as it is collected so that it is ready for analysis at the end of data collection.

Objective 6: Coding of sensory observation tasks for analysis.

Coding of the sensory observation tasks occurs as they are collected so that they are ready for analysis at the end of data collection.

Objective 7: Data entry, verification, and cleaning for analysis.

With the help of Prometheus Research, the Duke Center for Autism and Brain Development has created a database in which all data from this study is stored. Data from this study is entered into the Prometheus database, verified, and cleaned as it is collected, so that it is ready for analysis at the end of data collection.

f. Major Task 6: Data analysis of SOR and anxiety measures and publication.

Objective 1: Conduct data analysis.

We have begun preliminary analyses of the SOR and anxiety data on N=30 subjects. Preliminary analyses suggest that, in our convenience sample, 79% of children meet criteria for an impairing anxiety disorder, 21% of children score at least 1 standard deviation above the group mean for sensory over-responsivity (SOR group), and 100% of children in the SOR group also meet criteria for an anxiety disorder, however only 30% of children who meet criteria for an anxiety disorder are in the SOR group. Additionally, the number of anxiety symptoms is positively correlated with parent reported SOR scores.

Objective 2: Interpret results and prepare and submit manuscript for publication – begins in year 3.

Preliminary analyses provide early support for our hypothesis of a link between SOR and anxiety. Importantly, not all children with anxiety were in the SOR group. This supports our hypothesis that there is a secondary factor (we hypothesized that to be attentional differences) that moderates the relationship between SOR and anxiety in children with autism.

Specific Aim 2 Evaluate whether anxiety symptoms/disorders mediate the relationship between SOR and a wide range of negative outcomes that have been associated with SOR, namely, levels of impaired adaptive behavior, challenging behaviors (e.g. irritability, aggression), GI symptoms and parental stress

a. Major Task 1: Data analysis of comprehensive set of measures and publication

Objective 1: Conduct data analysis.

We have begun preliminary analyses of relationship between negative outcomes and both SOR and anxiety. Evaluation of the extent to which anxiety symptoms mediate the relationship between SOR and negative outcomes will begin once all data has been collected. Preliminary results support a relationship between observational measures of SOR and several negative outcomes, including picky eating and adaptive social behavior. Similarly, anxiety is related to increased sleep problems in our cohort.

Objective 2: Interpret results and prepare and submit manuscript for publication – begins in year 3.

Preliminary analyses provide early support for a link between SOR, anxiety, and negative outcomes.

Specific Aim 3. Evaluate whether attentional control, as assessed by a visual attention-shifting task and event-related potentials (ERPs) to a fearful facial expression, moderate the relationship between SOR and anxiety symptoms/disorders.

b. Major Task 1: Automated coding of visual attention task from videotapes.

Objective 1: Apply and calibrate algorithm for data capture – Completed in year 2, quarter 2.

Objective 2: Apply automated coding to videotapes.

All videos that have been collected as part of this study will be processed through the automated coding algorithm once that algorithm has been calibrated to our study population. Videos that are captured after algorithm calibration will be analyzed as data is collected.

Objective 3: Enter data for analysis.

The data from the automated coding analyses will continue to be deposited in our Center database as it is acquired.

c. Major Task 2: Data analysis of attention measures and publication.

Objective 1: Conduct data analysis of eye-tracking and automated coding data – begins in year 3.

Both parent reported and observational measures of sensory hyperresponsivity were associated with worse scores on the Shifting scale of the BRIEF-P, a parent report measure of attentional shifting. Parent reported sensory hyporesponsivity was also associated with greater dysfunction in the Shifting scale, however this relationship did not remain significant when controlling for age and IQ. Parent reported sensory hyporesponsivity was correlated with higher scores on the Inhibition scale of the BRIEF-P. Finally, emotional control was associated with parent reported hyper- and hyporesponsivity. ADOS severity was not associated with degree of sensory challenges or executive dysfunction.

Objective 2: Interpret results and submit manuscript for publication – begins in year 3.

Preliminary results suggest a relationship between SOR and attention in our participants.

d. Major Task 3: Data analysis of SOR measures (parent report, observation, ERP) and publication.

Objective 1: Conduct data analysis of auditory ERP data and SOR data based on parent report and observation data– begins in year 3.

Objective 2: Interpret results and submit manuscript for publication – begins in year 3.

C. Opportunities for training and professional development the project has provided

This project has provided training to individuals at a number of levels, including undergraduate, graduate, and post-graduate trainees.

Undergraduate Training: Logan Beyer, a Duke University undergraduate student, has been receiving course credit as an Independent Study student on this project since the beginning of the project in September 2014. In addition, a second independent study student, Jacqueline Emerson, joined the study in January 2016. Both Ms. Beyer and Ms. Emerson have received training in autism, anxiety, sensory processing, EEG and eye-tracking data acquisition and analysis, as well as general training in the day-to-day activities associated with scientific research. Additionally, the current funding and associated project have provided both Ms. Beyer and Ms. Emerson with training in scientific writing and principles of scientific data dissemination.

Graduate Training: Kathryn Williams, a graduate student under Dr. Grace Baranek at UNC Chapel Hill, and Adrianne Harris, a graduate student under Drs. Helen Carpenter, Geraldine Dawson, and Nancy Zucker at Duke University, have received training in observational assessment of sensory processing in children with autism as a result of this award. They have also gained experience with study management and oversight.

Post-Graduate Training and Professional Development: Additional training and professional development has been provided to Dr. Kimberly Carpenter, PI of this project. As a result of this project, Dr. Carpenter received training in (a) observational assessment of autism symptoms (ADI and ADOS) and sensory processing (SPA and TDDT) assessment in young children, (b) parent interviewing skills (ADI and PAPA), (c) EEG and eye-tracking data collection and analysis, (d) mentorship of undergraduate and graduate students, and (d) study and personnel management. Additionally, as a direct result of the work supported by this grant, Dr. Carpenter successfully competed for a 2015 NARSAD Young Investigator Award, which supports the research and professional development of early career scientists. She was also promoted to a faculty position within the Department of Psychiatry at Duke University while leading this study.

D. Dissemination of results to communities of interest

Preliminary results from the pilot study on ERP responses were presented at the 2016 North Carolina Psychological Association Undergraduate Research Conference, by Ms. Logan Beyer in a poster entitled "Updated Methodologies and Preliminary Data Analysis of Sensory Over-Responsivity in Children with Autism" based on the pilot ERP studies. This event is meant to disseminate undergraduate research projects to undergraduates and professionals from around North Carolina.

In addition to scientific presentations, information about this study has been presented at a number of community events, such as meetings of the Durham chapter of the Autism Society of North Carolina.

Finally, an abstract highlighting preliminary findings looking at the interaction between sensory over-responsivity and executive functions, namely attention shifting and inhibition, was submitted to the 2017 International Meeting for Autism Research (IMFAR).

E. Plans for next reporting period to accomplish goals

Specific Aim 1. Evaluate the relationship between SOR and anxiety symptoms/disorders in a sample of 3-5 year old children with ASD using parent report, observational, and neurophysiological measures.

e. **Major Task 1: Prepare regulatory documents and research protocol for IRB and HRPO Approval – completed in year 1.**

f. **Major Task 2: Hiring and training of study personnel on observational measures – completed in year 1.**

g. **Major Task 3: Set up, test, calibrate and pilot experimental measures of attention and neurophysiology – completed in year 1.**

h. **Major Task 4: Participant recruitment and launch of testing.**

Objective 1: Provide information and flyers about study to all recruitment sites.

Flyers and information about this study will be distributed throughout the enrollment period of this study.

Objective 2: Begin screening and enrolling participants in study – completed in year 1.

Objective 3: Maintain reliability and quality control on all measures.

Training to ensure reliability of the assessments is ongoing. Study staff attend monthly ADOS reliability sessions, as well as monthly reliability sessions for the sensory assessments, which take place at the UNC site for this study.

Objective 4: Target enrollment of 30 participants for year 1 reached – completed in year 2.

i. **Major Task 5: On-going enrollment and testing of participants and data collection and processing.**

Objective 1: Continue active recruitment through on-going communication with recruitment sites

We will continue to receive study referrals from the Duke Center for Autism and Brain Development subject registry and distribute study information at all local autism events (e.g. Walk Now for Autism Speaks, Autism Society of North Carolina Walk, etc.). We have also added the UNC email listerv as an added mode of recruitment. This listserve targets all individuals with a UNC email address.

Objective 2: Maintain reliability and quality control on all measures.

Training to ensure reliability of the assessments is ongoing. Study staff attend monthly ADOS reliability sessions, as well as monthly reliability sessions for the sensory assessments, which take place at the UNC site for this study

Objective 3: Edit and process EEG data for analysis.

We will edit and process the EEG data as it is collected so that it is ready for analysis at the end of data collection.

Objective 4: Process eye-tracking data for analysis.

We will edit and process the eye-tracking data as it is collected so that it is ready for analysis at the end of data collection.

Objective 5: Coding of sensory observation tasks for analysis.

We will code the sensory observation tasks as they are collected so that they are ready for analysis at the end of data collection.

Objective 6: Data entry, verification, and cleaning for analysis.

With the help of Prometheus Research, the Duke Center for Autism and Brain Development has created a database in which all data from this study will be stored. Data from this study is entered into the Prometheus database, verified, and cleaned as it is collected, so that it is ready for analysis at the end of data collection.

Objective 7: Target enrollment of 100 participants by end of Q1 of third year reached.

We have enrolled 48 subjects and have additional subjects scheduled through November. We will continue to actively recruit subjects through the first two quarters of year 3 in an effort to reach our goal of 100 participants.

j. Major Task 6: Data analysis of SOR and anxiety measures and publication.

Objective 1: Complete analysis of SOR and anxiety measures.

As highlighted above, we have begun preliminary analyses of SOR and anxiety in this study. As we close out data collection in year 3, we will finalize all data analyses in preparation for interpretation and publication.

Objective 2: Interpret results and prepare and submit manuscript(s) for publication.

Our focus in quarter 3 of the upcoming year of the grant will be the interpretation of data collected in this study and preparation of manuscripts.

Objective 3: Publish results of study on risk factors for anxiety in young children with ASD.

Our focus in the final quarter of this grant will be the submission of the results of the study for publication.

Specific Aim 2 Evaluate whether anxiety symptoms/disorders mediate the relationship between SOR and a wide range of negative outcomes that have been associated with SOR, namely, levels of impaired adaptive behavior, challenging behaviors (e.g. irritability, aggression), GI symptoms and parental stress – begins in year 3.

a. Major Task 1: Data analysis of comprehensive set of measures and publication.

Objective 1: Complete analyses on anxiety as a mediator of the impact of SOR on negative outcomes for children with ASD

A manuscript highlighting our preliminary results supporting anxiety as a mediator of the impact of SOR on negative outcomes for children without ASD is in preparation. The identical analyses will be implemented in quarter 3 of the upcoming year on data acquired under the current grant. Additionally, as outlined above, we have begun preliminary data analysis looking at the relationship between SOR, anxiety, and negative outcomes and have promising early results.

Objective 2: Interpret results and prepare and submit manuscript(s) for publication.

Our focus in quarter 3 of the upcoming year of the grant will be the interpretation of data collected in this study and preparation of manuscripts.

Objective 3: Publish results of study on risk factors for anxiety in young children with ASD.

Our focus in the final quarters of this grant will be the submission of the results of the study for publication.

Specific Aim 3 Evaluate whether attentional control, as assessed by a visual attention-shifting task and event-related potentials (ERPs) to a fearful facial expression, moderate the relationship between SOR and anxiety symptoms/disorders.

a. Major Task 1: Automated coding of visual attention task from videotapes - Work to be conducted by Jordan Hashemi under the supervision of Dr. Sapiro in collaboration with Dr. Carpenter.

Objective 1: Apply and calibrate algorithm for data capture – ongoing.

Our collaborators have been actively applying and calibrating the video coding algorithms for data capture on unrelated datasets. As we collect data as part of the current study, these algorithms will be calibrated to our subject population.

Objective 2: Apply automated coding to videotapes.

All videos that have been collected as part of this study will be analyzed as data is collected.

Objective 3: Enter data for analysis.

The data from the automated coding analyses will continue to be deposited in our Center database as it is acquired.

b. Major Task 2: Data analysis of attention measures and publication.

Objective 1: Complete data analysis of all eye-tracking and automated coding data

An abstract highlighting preliminary results from the current study suggesting that different patterns of sensory challenges are correlated with distinct executive dysfunctions, as measured with parent report, in young children with ASD was submitted to the 2017 IMFAR meeting. This data supports our hypothesis that there is a link between executive functions, specifically the ability to shift attention, and sensory over-responsivity in children with autism. As we complete collection of our eye-tracking measures in the 2nd quarter of the upcoming year, we will build upon these encouraging preliminary results, which were based on parent reported executive function, by adding the data from our eye-tracking paradigm, which will provide a neurophysiological measure of attention directly in our participants.

Objective 2: Interpret results and prepare and submit manuscript(s) for publication.

Our focus in quarter 3 of the upcoming year of the grant will be the interpretation of data collected in this study and preparation of manuscripts.

Objective 3: Publish results of study on risk factors for anxiety in young children with ASD.

Our focus in the final quarter of this grant will be the submission of the results of the study for publication.

c. Major Task 3: Data analysis of SOR measures (parent report, observation, ERP) and publication.

Objective 1: Conduct data analysis of auditory ERP data and SOR data based on parent report and observation data

Preliminary analysis of our ERP data from this study were presented at a regional conference for undergraduate researchers. Additionally, as highlighted above, analysis of the parent report and observational measures of SOR have begun with preliminary data submitted to the IMFAR. As we complete collection of our ERP and SOR measures in the 2nd quarter of the upcoming year, we will utilize the data analysis pipelines developed as part of our preliminary analyses to analyze the full dataset.

Objective 2: Interpret results and prepare and submit manuscript(s) for publication.

Our focus in quarter 3 of the upcoming year of the grant will be the interpretation of data collected in this study and preparation of manuscripts.

Objective 3: Publish results of study on risk factors for anxiety in young children with ASD.

Our focus in the final quarter of this grant will be the submission of the results of the study for publication.

IV. Impact

A. Impact on the development of the principal discipline(s) of the project

The immediate impact of this project will be the identification of early risk factors for anxiety in ASD. Currently, treatments focus on helping older children and adults with ASD who already suffer from an anxiety disorder, rather than addressing anxiety symptoms when they first begin or even preventing the onset of an anxiety disorder. In fact, very little research on anxiety in preschool age children with ASD has been conducted. If an association between SOR and anxiety is confirmed, this study may ultimately inform interventions that focus on prevention, rather than treatment, of anxiety. Specifically, early behavioral interventions could be customized for children at risk for anxiety to include strategies that could prevent the development of anxiety, offering a more positive outcome for many people with ASD and their families. This study will shed light on the specific ways such interventions should be customized for children with ASD who are at risk for anxiety.

This project will also pilot and validate new methods for measuring SOR and attention that allow for more objective measurement of these behaviors. First, our early pilot study demonstrating a negligible impact of a low-volume cartoon on the P50 ERP response greatly extends the utility of the paired-click paradigm as a measure of SOR in populations of preschoolers with ASD. As researchers continue to explore development of anxiety in children with autism, the ability to use the paired click paradigm to tap relevant variables will likely prove invaluable. Unlike other standard measures of SOR, the paired click paradigm taps the neurobiological basis of sensory sensitivity, and is thus an essential complement to more observational assessments. Second, the use of automated methods for measuring attention will allow assessment of these behaviors in a more efficient, scalable, and cost-effective manner. Both of these methodological advances will facilitate the translation of findings from the research lab into clinical and educational settings.

B. Impact on the on other disciplines

Sensory over-responsivity (SOR) is characterized by heightened and unusual reactivity to sensory stimuli, such as touch and sound. Community studies suggest that SOR affects up to 16% of school-age children. SOR is also prevalent across a number of neurodevelopmental and psychiatric disorders and recent evidence suggests that it may be a risk factor for emotion dysregulation and anxiety in not only ASD, but also other disorders such as ADHD and anorexia nervosa. This suggests that there is a shared relationship between SOR and anxiety, yet the mechanism underlying this relationship remains unknown. Thus, although the current project focuses on young children with ASD, the findings will have implications for understanding the relationship between SOR, anxiety, and negative outcomes and the development of novel approaches for treating anxiety disorders across the lifespan.

C. Impact on technology transfer

Nothing to report.

D. Impact on society beyond science and technology

Firsthand accounts from people with autism spectrum disorder (ASD) illustrate the impact of sensory over-responsivity (SOR) and anxiety on everyday life. Both SOR and anxiety are extremely common among people with ASD and both have been shown to significantly affect quality of life for the person with ASD and their families. SOR has been associated with higher rates of avoidance, aggression, food selectivity, and lower levels of social and adaptive behavior. A recent study found that early SOR symptoms in a child with ASD can lead to higher levels of family stress and restrictions in family life activities. SOR can also have an impact on oral care, both in the home and dental office. Similarly, the presence of an anxiety disorder has been shown to negatively affect family functioning, friendship development, and school functioning. Later in life, anxiety places adolescents with ASD at risk for social isolation and employment difficulties. Furthermore, higher rates of SOR and anxiety are associated with chronic GI symptoms and sleep disturbance. The results of the current study have the potential of directly influencing the policy and practice around the early identification and early treatment of SOR and anxiety in children with ASD.

V. Changes/Problems

A. Changes in approach and reasons for change

In the last year we switched our measure of GI function from the ATN-GI to the Peds-QL GI Symptoms Inventory. Although these two measures acquire similar information about GI function, the decision to switch to the Peds-QL form was made due to the availability of standardized scoring algorithms for this form, which are not available for the ATN-GI. No other changes to approach were made.

B. Actual or anticipated problems or delays and actions or plans to resolve them

We have had some turnover in staff within the second year of the study. As we trained new staff on the measures, data collection slowed a bit. All new staff have now been trained to reliability on all measures and data collection has again increased. To make up for delays caused by staff changes, we will continue to collect data into the second quarter of the 3rd year of the study.

C. Changes that had a significant impact on expenditures

Nothing to Report

D. Significant changes in use or care of human subjects

Nothing to Report

E. Significant changes in use or care of vertebrate animals

Nothing to Report

F. Significant changes in use or care of biohazards and/or select agents

Nothing to Report

VI. Products

A. Publications, conference papers, and presentations

a. Journal publications.

Nothing to Report

d. Books or other non-periodical, one-time publications.

Nothing to Report

e. Other publications

Nothing to Report

f. Conference papers

Nothing to Report

g. Presentations

h. Carpenter KLHC (2016, May) “Anxiety and Autism: Prevalence, Presentation, and Associated Factors.” Presentation to the Duke Occupational Therapist Group. Duke University Medical Center, Durham, NC.

Beyer L, Dawson G, Egger HL, and Carpenter KLH (2016, April) “Updated Methodologies and Preliminary Data Analysis of Sensory Over-Responsivity in Children with Autism.” Poster presented at the NC Psychology Undergraduate Conference at the Harris Conference Center, Charlotte, NC.

Beyer L, Kwak H, Dawson G, Murias M, and Carpenter KLH (2016, April) “Operationalizing Sensory-Sensitivity in Typically Developing Adults with Both EEG and Survey Measures.” Poster presented at the Visual Thinking Symposium at Duke University, Durham, NC.

Carpenter KLHC (2016, February) “Anxiety and Autism: Prevalence, Presentation, and Associated Factors.” Presentation at the Duke Center for Autism and Brain Development Autism Clinical Seminar. Duke University Medical Center, Durham, NC.

Baranek, G. T. (2015, October). Sensory Features in Children with Autism: Regulatory Mechanisms and Effects on Daily Life. Invited Lecture presented to the SPD Foundation, Orlando, FL. (Oct. 9).

Carpenter KLH, Dawson G, Egger HL, Baranek G (2015, June) “Sensory Over-Responsivity and Anxiety in Autism.” Poster presented at the grand opening of the Duke Center for Autism and Brain Development, Durham, NC.

Beyer L, Dawson G, Egger HL, and Carpenter KLH (2015, April) “Updated Methodologies and Preliminary Data Analysis of Sensory Over-Responsivity in Children with Autism.” Poster presented at the Visual Thinking Symposium at Duke University, Durham, NC.

Baranek, G. T. (2015, February). Understanding the Nature and Impact of Sensory Features in Children with ASD. Invited lecture presented at the 14th Annual Alabama Autism Conference, University of Alabama, Tuscaloosa, AL.

B. Website(s) or other Internet site(s)

http://autismcenter.duke.edu/research/sensory-processing-and-anxiety-preschool-age-children-autism-spectrum-disorder

C. Technologies or techniques

Nothing to Report

D. Inventions, patent applications, and/or licenses

Nothing to Report

E. Other Products

Nothing to Report

VII. Participants & Other Collaborating Organizations

A. Individuals that have worked on the project

Name: Geraldine Dawson, PhD, FAPA, FAPS
Project Role: Principal Investigator
Nearest person month worked: 1
Contribution to Project: No Change

Name: Helen Egger, MD
Project Role: Partnering Principal Investigator
Nearest person month worked: 1
Contribution to Project: As of 9/11/2016, Dr. Egger is no longer a partnering PI on this study. She remains on as a collaborator as will take part in the monthly team meetings through the end of the grant.

Name: Grace Baranek, PhD, OTR/L, FAOTA
Project Role: Partnering Principal Investigator
Nearest person month worked: 1
Contribution to Project: No Change

Name: Kimberly Carpenter, PhD
Project Role: Partnering Principal Investigator; Project Coordinator – Duke Site
Nearest person month worked: 5
Contribution to Project: As of 9/11/2016, Dr. Carpenter has assumed the role of Partnering PI on this project. As such, she has taken on the added responsibilities of ensuring the fiscal integrity of the grant; Training and managing staff involved in the early childhood mental health data collection (PAPA); Designing and implementing the eye-tracking attention-shifting paradigm.

Name: Lauren DeMoss, MS, OTR/L
Project Role: Project Co-Coordinator – Duke Site
Nearest person month worked: 5
Contribution to Project: As of 7/28/2016, Ms. DeMoss is no longer with the study.

Name: Logan Beyer
Project Role: Undergraduate Student
Nearest person month worked: 2
Contribution to Project: No Change

Name: Brian Small, MS
Project Role: Interviewer
Nearest person month worked: 1
Contribution to Project: No Change

Name: Hannah Riehl, BA
Project Role: Research Assistant
Nearest person month worked: 3
Contribution to Project: Contribute to DoD related activities (e.g. preparation of quarterly report, submission of human research documents to HRPO); Participate in the ongoing training in early childhood mental health assessment, sensory processing measures, and ERP/EEG data collection; Help supervise

undergraduate and graduate research assistants; Coordinate recruitment efforts; Refine study protocol; Attend weekly Duke team meetings and monthly all-site meetings.

Name: Elizabeth Glenn, BS
Project Role: Research Assistant
Nearest person month worked: 1
Contribution to Project: Contribute to DoD related activities (e.g. preparation of quarterly report, submission of human research documents to HRPO); Participate in the ongoing training in early childhood mental health assessment, sensory processing measures, and ERP/EEG data collection; Help supervise undergraduate and graduate research assistants; Coordinate recruitment efforts; Refine study protocol; Attend weekly Duke team meetings and monthly all-site meetings.

Name: Ashley Freuler, PhD
Project Role: IRB coordination – UNC
Nearest person month worked: 1
Contribution to Project: No Change

Name: John Bulluck, BS
Project Role: Research Associate, UNC
Nearest person month worked: 1
Contribution to Project: No Change

Name: Kathryn Williams, MS
Project Role: Graduate RA, UNC
Nearest person month worked: 1
Contribution to Project: No Change

B. Changes in the active other support of the PD/PI(s) or senior/key personnel

Dr. Egger stepped down as PI of award W81XWH-14-1-0527. Dr. Carpenter has assumed role as PI on this award and will receive the support originally allocated to Dr. Egger in accordance with her increased role on this project.

C. Other organizations involved as partners

Organization name: Center for Autism and Brain Development, Duke University Medical Center
Location of organization: Durham, NC
Partner's contribution to the project: Collaboration

Organization name: Center for Developmental Epidemiology, Duke University Medical Center
Location of organization: Durham, NC
Partner's contribution to the project: Collaboration

Organization name: Pratt School of Engineering, Duke University
Location of organization: Durham, NC
Partner's contribution to the project: Collaboration

Organization name: Duke Pediatric Primary Care
Location of organization: Durham, NC

Partner's contribution to the project: Recruitment support

Organization name: Duke Lenox Baker Children's Health Center
Location of organization: Durham, NC
Partner's contribution to the project: Recruitment support

Organization name: Autism Society of North Carolina
Location of organization: Raleigh, NC
Partner's contribution to the project: Recruitment support